



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2017-N-7012]**

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-NEW and title “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics

OMB Control Number 0910-NEW

This information collection supports the above captioned Agency guidance document. In the *Federal Register* of July 8, 2016 (81 FR 44611), FDA announced the availability of a draft guidance for industry entitled “Use of Public Human Genetic Variant Databases To Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics,” and included an analysis of the associated information collection.

The draft guidance described FDA’s considerations in determining whether a genetic variant database is a source of valid scientific evidence that could support the clinical validity of an NGS-based test. This draft guidance further outlines the process by which administrators<sup>1</sup> of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases. The draft guidance also recommends that, at the time of recognition, the database administrator make information regarding policies, procedures, and conflicts of interest publicly available and accessible on the genetic variant database’s website.

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<sup>1</sup> FDA acknowledges that many databases may not use the term “administrator” or may have a committee of individuals that oversee the database. Therefore, for the purpose of this guidance, a genetic variant database administrator is the entity or entities that oversee database operations.

Based on our experience and the nature of the information, we estimate that it will take an average of 80 hours to complete and submit an application for recognition. We estimate that maintenance of recognition activities will take approximately one-fourth of that time (20 hours) annually. We estimate that it will take approximately 1 hour to post the information on the website.

Respondents are administrators of genetic databases. Our estimate of five respondents per year is based on the current number of databases that may meet FDA recommendations for recognition and seek such recognition.

FDA received 36 comments on the draft guidance, none of which pertained to the information collection burden estimate.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Application for recognition of genetic database	5	1	5	80	400

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Maintenance of recognition activities	5	1	5	20	100

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Public disclosure of policies, procedures, and conflicts of interest	5	1	5	1	5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The draft guidance also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the Paperwork Reduction Act

of 1995 (44 U.S.C. 3501-3520). The collections of information in the guidance document “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910-0756. The collections of information regarding premarket submissions have been approved as follows: the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120 and the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231.

Dated: January 11, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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